Ontario Health / Santé Ontario

eClaims
Demandes de remboursement en ligne

Eligibility Form

Daratumumab in combination with Bortezomib, Lenalidomide and Dexamethasone - Newly Diagnosed Transplant Eligible Multiple Myeloma

(This form should be completed before the first dose is dispensed.)

1. Patient Profile

* Surname: .....

* Given Name: .....

* OHIN: ..... * Chart Number: .....

* Postal Code: .....

* Height (cm): ..... * Weight (kg): .....

* BSA (m^2): ..... * Gender: ○ Male ○ Female ○ Other

* Date of Birth: ....
Day Month Year

* Site:

* Attending Physician (MRP- Most Responsible Physician): .....

Requested Prior Approval ☐ Yes * Patient on Clinical Trial ○ Yes ○ No

Specify Trial:
○ Clinical Trial 1 ○ Clinical Trial 2
○ Clinical Trial 3 ○ Other

Other (specify): .....

Specify Arm:
○ Standard of care arm ○ Experimental arm
○ Blinded / Unknown

Prior Approval Request

* Select the appropriate prior approval scenario:

- ○ 1-Unknown primary (submit pathology report and clinic note)
- ○ 2-Clinical document review (identify the patient history that needs to be reviewed against eligibility criteria in Additional Comments below)
- ○ 3-Regimen modification - schedule (complete questions a and b)
- ○ 4-Regimen modification - drug substitutions (complete questions a and c)
- ○ 5-Withholding a drug in combination therapy from start of treatment (complete questions d, e and f)
- ○ 6-Maintenance therapy delay (submit clinic note)
- ○ 7-Prior systemic therapy clinical trials (complete question g)
- ○ 8-Modification due to supply interruption/drug shortage
- ○ Other (specify)

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All relevant supporting documentation must be submitted at the time of prior approval. Documentation may include a pathology report, clinic note, and/or CT scans.

a. Co-morbidities / toxicity / justification:

.....

b. Intended regimen schedule: .....

c. Intended regimen: .....

d. Drug(s) to be held: .....

e. Rationale for holding drug(s): .....

f. Intention to introduce drug at a later date? ☐ Yes

g. Prior clinical trial identifier (e.g., NCT ID, trial name) and treatment description (e.g., arm, drug/regimen): .....

h. Anticipated date of first treatment: ....
Day Month Year

i. Additional comments:

2. Eligibility Criteria

Daratumumab will be used for the treatment of adult patients with previously untreated multiple myeloma who are eligible for an autologous stem cell transplant. ☐ Yes

Daratumumab will be used in combination with bortezomib, lenalidomide and dexamethasone in the induction and consolidation phases then in combination with lenalidomide as maintenance.

Patients must have a good performance status.

Patients must not have clinical signs of meningeal involvement of multiple myeloma.

3. Baseline Information

a. ECOG Performance Status at the time of enrolment ○ 0 ○ 1 ○ 2

b. Is the patient transitioning from a private payer or compassionate program? ○ Yes ○ No

c. if yes, please indicate the funding source
○ Private payer
○ Manufacturer patient support program

d. if yes, please indicate the date of the last administered dose
Day Month Year

4. Funded Dose

Cycles 1 to 2 (given in combination with bortezomib, lenalidomide, and dexamethasone):
Daratumumab 1800 mg subcutaneously (SC) on day 1, 8, 15, and 22

Cycles 3 to 6 (given in combination with bortezomib, lenalidomide and dexamethasone):
Daratumumab 1800 mg SC on day 1 and 15

Cycles 7 and onwards (given in combination with lenalidomide only):
Daratumumab 1800 mg SC on day 1

Treatment should continue until (whichever comes first):

- Disease progression; OR
- Unacceptable toxicity; OR
- Achievement of a complete response (or better) and sustained minimal residual disease (MRD)-negativity for a minimum of 12 months after a minimum of 24 months of maintenance therapy with daratumumab plus lenalidomide. Once achieved, lenalidomide may be continued as monotherapy.

1 cycle = 28 days

[ST-QBP regimen code(s): BORTDEXALENA+DARA(SC); LENA+DARA(MNT-SC)]

5. Notes

1. Patients with plasma cell leukemia or secondary amyloidosis who are eligible for an autologous stem cell transplant would be eligible under this policy. Patients with primary light chain amyloidosis would not be eligible.

6. FAQs

1. **My patient is currently receiving daratumumab through a non-publicly funded means (e.g. patient support program, private insurance). Can my patient be transitioned to receive funding through the New Drug Funding Program (NDFP)?**

   Provided the eligibility criteria were met at the time of treatment initiation and the patient's disease has not progressed, your patient may be eligible for continued coverage through the NDFP.

2. **What is the process for transitioning my patient from a non-publicly funded program to NDFP funding?**

   If your patient meets all of the eligibility criteria outlined in this policy, please submit as a regular eClaims enrolment.

   Prior approval requests are reserved for instances where there is clinical uncertainty on eligibility. In these circumstances, please specify your reason(s) for uncertainty and upload the following:

   - A clinic note and imaging (if applicable) from treatment initiation, and
   - The most recent clinic note and imaging (if applicable).

   Please note: Patients who meet the NDFP eligibility criteria and are enrolled in the manufacturer's patient support program (PSP) are eligible to receive continued drug supply through the PSP until July 28, 2026, inclusive.

   After this date, patients who met the NDFP eligibility criteria at the point of treatment initiation are eligible to transition to NDFP funding for the remainder of their treatment course. Although sites may enroll their patient onto this policy at any time beforehand, any treatment claims submitted to eClaims that were given on or before the PSP transition date will be denied.

3. **My patient has initiated induction therapy with bortezomib, lenalidomide, and dexamethasone (VRd) or maintenance with lenalidomide. Can daratumumab be added?**

   On a time-limited basis, daratumumab may be added to VRd or to maintenance lenalidomide provided the patient has not progressed on treatment and they meet all of the eligibility criteria. Please submit as a prior approval request in eClaims including the most recent clinic note outlining the treatment history and response to treatment, if able to assess.

4. **My patient is intolerant to one of the components of the regimen. Can I continue therapy with the remaining agents?**

   Patients who are intolerant to one of the components of this regimen may continue therapy with the other agents until disease progression or unacceptable toxicity or achievement of a complete response (or better) and sustained MRD-negativity as noted above in the Funded Dose section.

5. **My patient stopped maintenance daratumumab after achieving MRD-negativity. Can daratumumab be restarted upon relapse?**

   Patients who discontinued maintenance daratumumab due to achieving MRD-negativity are eligible to restart daratumumab upon relapse provided the patient relapsed 90 days or greater after the last dose of daratumumab. Claims should be submitted under the same form used for the initial course of treatment.

6. **My patient stopped maintenance daratumumab after achieving MRD-negativity but is now MRD-positive. If my patient has no classical signs of disease progression, will retreatment with daratumumab be funded?**

   Patients who discontinued maintenance daratumumab due to achieving MRD-negativity but are now MRD-positive, and have no classical signs of biochemical, clinical, or radiographical disease progression, are eligible to restart daratumumab. Claims should be submitted under the same form used for the initial course of treatment.

Supporting Documents

None required at time of enrolment.

In the event of an audit or upon request, the following should be available to document eligibility:

- Clinic notes outlining patient and treatment history/response, as well as stem cell transplant eligibility.
- Blood work and imaging demonstrating no disease progression.
- Bone marrow aspirate(s) including MRD testing result(s).

Signature of Attending Physician (MRP-Most Responsible Physician): .....

....
Day Month Year